

REMARKS

Claims 1-46 are pending in the above-identified patent application and are subject to a restriction requirement.

I. AMENDMENTS TO THE CLAIMS

Minor amendments to the claims are made for clarity. No new matter is introduced thereby.

Claim 1 is amended to state the pH adjustment step as a clear and distinct method step. Support for this amendment is found, e.g., at page 12, lines 15-17, describing adjusting the pH.

Claims 11 and 24 are amended to clarify that the composition is made by the method.

Claim 21 is amended to state the Markush group in alternative language as required.

Accordingly, entry of these amendments is respectfully requested.

II. THE RESTRICTION REQUIREMENT

Restriction to one of the following inventions was required under 35 U.S.C. § 121:

Group I is claims 1-10 and 12-23, drawn to a method of preparing a topical solution containing a solvent and alcohol, classified in Class 514, subclass 772.

Group II is claims 10 and 24-37, drawn to a topical solution, classified in Class 424, subclass 772.

Group III is claims 38-46, drawn to a method of stimulating hair growth by topically applying a solution containing piperidinopyrimidine derivative, classified in Class 514, subclass 254.14.

As originally stated in the Restriction Requirement, claim 10 is listed in both Group I and Group II. However, claim 10 reads: "The method of claim 1, wherein said alcohol is ethyl alcohol." Claim 1 therefore is properly in Group I, drawn to a method of preparing a topical solution containing a solvent and alcohol. Claim 11 was not included in any of Group I, II, or III. Claim 11 reads: "A topical solution made [[from]] by the method recited in claim 1." Claim 11 therefore is properly in Group II, drawn to a topical solution. The following Response to the Restriction Requirement assumes that claim 10 is in Group I and claim 11 is in Group II. Clarification is requested.

The inventions were stated to be distinct for the following reasons:

The inventions of Group I and Group II were related as process of making and product made. The inventions were stated to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product; or (2) that the product as claimed can be made by another and materially different process. M.P.E.P. § 806.05(f). The Restriction Requirement stated that the product as claimed can be made by another and materially different process in that the ingredients can be simply mixed together.

The inventions of Group II and Group III were related as product and process of use. The inventions were stated to be distinct if either or both of the following

can be shown: (1) the process for using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used in a materially different process of using that product. M.P.E.P. § 806.05(f). The Restriction Requirement stated that the process for using the product as claimed can be practiced with another materially different product in that methods of stimulating hair growth are disclosed in the art that contain other hair growth active agents and/or contain lower amounts of minoxidil.

The Restriction Requirement has required restriction between product and process claims. Where Applicants elect claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a non-elected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined pursuant to 37 C.F.R. § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims need to be amended during prosecution to require the limitations of the product claim; failure to do so may result in the loss of the right to rejoinder. Additionally, the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. M.P.E.P. § 804.01.

### III. APPLICANTS' RESPONSE TO THE RESTRICTION REQUIREMENT

Applicants elect the invention of Group II, claims 11 and 24-37, drawn to a topical solution, for prosecution on the merits, with traverse.

The Restriction Requirement is traversed on the following grounds:

Firstly, the Examiner has not met the burden for demonstrating the necessity for restriction. M.P.E.P. § 803 requires for restriction both: (1) that the inventions are independent or distinct as claimed; and (2) that there would exist a “serious burden” on the Examiner if all of the claims were examined in one application. These requirements have not been met.

In fact, the subject matter of Groups I through III, claims 1-46 are sufficiently related to avoid restriction, because there would be no “serious burden” on the Examiner if all of the claims were examined together in one application. The essence of the invention is that a topical solution containing a solvent and alcohol with a piperidinopyrimidine derivative can be prepared and used for stimulating hair growth.

Accordingly, the subject matter of the invention is sufficiently interrelated that no serious burden on the Examiner would exist if all the claims were examined on the merits. That is because the relevant art involved, if any relevant art exists, largely overlaps for these claims. For example, any patents that describe a seemingly similar topical solution would, of necessity, also describe the preparation and use of that solution in order to meet the requirements of the first paragraph of 35 U.S.C. § 112 regarding adequacy of written description and the requirement that the disclosure be sufficient that one of ordinary skill in the art could both make and use the claimed invention without undue experimentation. (This statement is not to be taken as an admission that any such

patents or other relevant art exists or would make the pending claims anticipated or obvious; it is merely a statement about the requirements for patentability of such compositions.) Similarly, other publications, if in fact they exist, also would be expected to describe both the preparation and use of the compositions. (Again, this is not to be taken as an admission that any such publications exist.)

Moreover, 37 C.F.R. § 1.141(b) provides as follows: “Where claims to all three categories, product, process of making, and process of use, are included in a national application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though a showing of distinctness between the product and process of using the product can be made.” This provision means that, because the claims directed to the process of making should not properly be restricted from the claims directed to the product itself, the claims to the process of using the product should also be examined on the merits and the Restriction Requirement withdrawn.

Applicants do not traverse the Restriction Requirement on the grounds of lack of patentable distinctness. Rather, Applicants traverse the Restriction Requirement on the grounds that the inventions of Groups I through III are sufficiently related that restriction is not properly required, despite the existence of patentable distinctness.

Therefore, the Restriction Requirement is respectfully traversed and the Examiner is respectfully requested to withdraw the Restriction Requirement and to allow the examination of all of Groups I through III on the merits.


IV. CONCLUSION

In conclusion, Applicants elect the invention of Group II, claims 11 and 24-37, drawn to a topical solution, for prosecution on the merits, with traverse.

The Restriction Requirement is respectfully traversed and the Examiner is respectfully requested to withdraw the Restriction Requirement and allow the examination of all claims on the merits.

If any issues remain, the Examiner is respectfully requested to telephone the undersigned at (858) 200-0581.

Respectfully submitted,



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